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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,614	03/01/2000	GAIL PETUNA RISBRIDGER	229752000800	6186

7590 01/20/2006
MORRISON & FOERSTER LLP
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MCLEAN, VA 22102

EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/402,614	Applicant(s) RISBRIDGER ET AL.	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12-22-2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26,40-58,60-63,69,72-93,95,96,98 and 99 is/are pending in the application.
- 4a) Of the above claim(s) 1-26,40-57 and 92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58,60-63,69,72-91,93,95,96,98 and 99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1642

Re: Risbridger *et al.*

Date of priority: 04/23/1997

Response to Amendment

The After-Final Amendments filed 12-22-2005 in response to the Final Rejection of 12-28-2004 is acknowledged and has been entered.

Claims 1-26, 40-58, 60-63, 69, 72-93, 95-96, and 98-99 are pending.

Claims 1-26, 40-57, and 92 are currently withdrawn.

Claims 58, 60-63, 69, 72-91, 93, 95-96, and 98-99 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

New Rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1642

Claims 58, 60-63, 69, 72-91, 93, 95-96, and 98-99 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See also *Ex parte Forman*, 230 USPQ 546 (BPAI 1986).

The claims are broadly drawn to a method of screening a mammal comprising screening for the down regulation of "inhibin protein levels" wherein the down regulation of the inhibin protein levels relative to the inhibin protein levels of a normal mammal is indicative of the mammal having developed **prostate cancer** (Claim 58). The claimed method is further defined as a method of screening a mammal (or a method of screening a human- Claim 95) for prostate cancer comprising obtaining a biological sample and determining a level of an inhibin protein in said biological sample, and comparing said level determined with a level known to be indicative

Art Unit: 1642

of a normal mammal, wherein a down-regulation of said inhibin protein level in the biological sample relative to the inhibin protein level of a normal mammal is indicative of the mammal having developed prostate cancer (Claim 83).

The specification teaches (page 43) the down-regulation or complete absence of inhibin subunit protein levels (α N and α C) in a small sampling (12 patients) of human prostate cancer tissues compared to the presence of α N and α C inhibin subunits in adjacent non-malignant regions of the prostate. Similarly, the specification teaches that in situ hybridization was performed using tissue from 8 patients with histological grade 4/5 prostate cancer and confirmed the pattern of protein inhibin localization. Hence, α -subunit gene expression was detected in basal cells in 7 of 8 patients in non-malignant regions and in both basal and secretory cells in some patients while malignant tumor cells in adjacent regions of the same patient biopsies did not display any α -subunit gene expression.

However, upon later re-evaluation co-inventor Risbridger (Risbridger *et al.* "Re-evaluation of inhibin α subunit as a tumour suppressor in prostate cancer". Molecular & Cellular Endocrinology, 2004, Vol. 225, pages 73-76) teach that an expanded study (approximately 174 prostate cancer specimens) of inhibin α subunit protein expression in prostate cancer revealed the opposite (abstract). That is, unexpectedly, in the majority of cases (89%) there was **more**, rather than less, intense staining of inhibin α subunit in cancer compared to the non-malignant tissue (page 75, 1st column). In their own words, the authors state (page 75, 1st column, 2nd full para.) "The results of the study were unexpected and did not support the previous evidence that inhibin α subunit was down regulated in men with prostate cancer."

Art Unit: 1642

Given the evidence set forth in the immediately preceding paragraph, it appears that one of ordinary skill in the art would not be able to successfully detect and or screen prostate cancer by detecting a down-regulation or absence of inhibin protein levels. Thus, it would require undue experimentation to practice the invention as claimed.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN

A handwritten signature in black ink, appearing to read "Gary B. Nickol". The signature is written in a cursive, flowing style.

**GARY B. NICKOL, PH.D.
PRIMARY EXAMINER**